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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SIMS, JASON M	
ART UNIT	**PAPER NUMBER**
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/686,263	SYROID ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/18/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/18/2007 has been entered.

Claims 6-49 are the current claims hereby under examination.

Upon viewing the amended claims, it is noted the broadness of said claims do not discuss any particular configuration and the intended limitations are not given patentable weight as discussed below.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/18/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 102

The following rejection is being newly made:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 8-10, 12-30, 35, and 41-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Howson et al (US P/N 5,088,981).

The claims are directed to a system for data representation comprising:

- A drug delivery system;
- A data stream device;
- A drug display monitor in communication with the data stream device, the drug display monitor configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject, wherein the present probability of effectiveness includes a correlation of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamic effectiveness based on modeled pharmacodynamic data.

Howson et al ('981) discloses a system for data representation comprising a drug delivery system (52, 54) a data stream device (50) in communication with the drug delivery device system (52, 54) and a drug delivery display monitor (28), in communication with a data stream device (50), see figures 1 and 2. Furthermore, Howson et al ('981) discloses that the drug delivery system comprises a simulator,

which simulates bolus, infusion and anesthetic drug administration (col. 4 line 3). Moreover, Howson et al ('981) discloses a drug display monitor (28) comprising a data decoder (20) receiving data from the data stream device (50); a dosage calculator (32) receiving decoded data from the data decoder; a drug modeler (26) and normalizer (24) receiving calculated data from the data decoder; a storage device (16), receiving drug and dosage data from the drug modeler and normalizer; and a display generator (28), wherein the display generator produces a display of more than one drug dosages, drug name, past, present and predicted drug site concentration and effect site concentration in three-dimensional form and a system for data representation comprising a processor (16), computing drug models, producing an internal representation of drug display data and decoding a data stream; a memory unit in communication with the processor; a graphics adapter (24c) in communication with the processor and a display monitor in communication with the graphics adapter, see figures 1 and 2 and col. 13, 14 and 15. Additionally, Howson et al ('981), at col. 7, lines 5-65 discloses how the drug concentrations and dosages are calculated based on information obtained from databases, in real time, that include patient history information, drug database information, and pharmacokinetic algorithms to provide accepted drug dosage ranges, drug to drug interaction, and mathematical support for dose-response information, which represents a monitor that is configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject. Moreover, a monitor that is configured to depict present and future drug dosages, which

uses databases and algorithms to aid in calculating a proper drug dosage, is depicting a probability of effectiveness in the form of a drug dosage. The calculated drug dosage for a particular patient is based on that patient's history information, which may include past treatment history in coordination with drug database information and pharmacokinetic algorithms, and the result is a proper drug dosage to be delivered to cause a particular drug concentration in the patient, which has a particular real-time probability of effectiveness based on current and past available data. Howson et al ('981) further discusses at col. 10, lines 55-67 and col. 12, lines 20-66, the design of profiles for patient drug delivery and how these profiles, when complete, have the computer validate the profile to ensure that arithmetic, procedural, or conceptual errors have not been made, and the profile can even be simulated or tested in software prior to the instructions being executed, which reads on the amended phrase "probability of effectiveness." Howson et al ('981), at col. 15 and 16, further discloses a system that can be used to manage each of the infused drugs and other drugs as well and the user can ask the computer to use pharmacokinetic algorithms to help derive optimum profiles for the patient. The system is a comprehensive medication management system, which is configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject.

Howson et al. does not explicity teach a drug display monitor configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of

the one or more drugs in the subject, wherein the present probability of effectiveness includes a correlation of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamic effectiveness based on modeled pharmacodynamic data.

However, the examiner views a computer monitor being capable and already configured to displaying any type of data stream. In particular, Howson et al. does teach a monitor that displays real time drug effectiveness data streams. Therefore, it is inherent that a computer monitor is configured and capable of displaying data streams as it is the definitive function of the monitor to do so. Upon viewing the claims, the intended use limitations are not given weight because they are only limiting to the data prior to becoming part of the data stream, but the resulting data stream is just that, a data stream, wherein the monitor is inherently configured and capable of displaying said data stream. Moreover, a monitor is capable of displaying data streams, wherein a data stream may be any type of probability and specifically it may be a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject, wherein the present probability of effectiveness includes a correlation of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamic effectiveness based on modeled pharmacodynamic data and therefore be displayed on the monitor taught by Howson et al.

Howson et al. teaches a processor already configured to processing drug model data. However, Howson et al. does not explicitly teach a processor configured for such

functionality as causing the graphics adapter and the display monitor to graphically depict a percent likelihood that the at least one drug has a desired effect.

However, the examiner views a processor, which is already capable and configured to displaying drug model data will inherently be configured such functionality as causing the graphics adapter and the display monitor to graphically depict a percent likelihood that the at least one drug has a desired effect. In particular, Howson et al. does teach a processor that inherently causes the graphics adapter to display real time drug effectiveness data streams. Therefore, it is inherent that the processor is configured and capable of performing such functionality as recited in the claims. Upon viewing the claims, the intended limitations are not given weight because they are only limiting to the data prior to becoming part of the data stream, but the resulting data stream is just that, a data stream, wherein the processor is inherently configured and capable of processing said data stream.

Claim Rejections - 35 USC § 103

The following rejection is being newly made and incorporating new reasoning as stated above:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al ('981) as applied to claims 6, 8-10,12-15, 20-21, 35 and 41-43 above, and further in view of Teeple Jr. U.S. Patent Number 5,925,014.

The claims are drawn to a system for data representation comprising a drug delivery system, a data stream device and a drug display monitor, wherein the drug delivery system comprises an infusion pump, a gas administration machine, and one or more bolus injection apparatus and the simulator simulates anesthetic drugs.

Howson et al ('981) discloses the drug delivery system as described above in reference to claim 6 and further comprising an infusion pump (14 see col. 10 line 13).

Howson et al ('981) fails to disclose an anesthetic administration machine and one or more bar coded syringes.

Teeple Jr. discloses an anesthetic administration machine (30 see figure 3); and one or more bar coded syringes (31-33 see figure 3).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the drug delivery system of Howson et at ('981) by

incorporating anesthesia administration and bar coded syringes as taught by Teeple Jr. ('014) in order to insure that the proper drug mix is achieved, reducing if not eliminating the possibility for human error (Teeple Jr. col. 4 line 67).

Claims 31-34 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al as applied to claims 6, 8-10,12-15, 20-21, 35 and 41-43 above, and further in view of Johnson et al and further in view of Teeple Jr.

Howson and Johnson disclose the device as described above, but fail to explicitly disclose that the components are sedative, neuromuscular blocker, anesthetic agents, and analgesic agents (col. 10 line 27 and col. 1 line 19) and that the display monitor configured to depict a present probability of effectiveness is one wherein the effectiveness of at least one drug in a subject at: causing the subject to lose consciousness; eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain; or causing a measurable level of muscle relaxation.

Anesthetic agents, which would be administered for purposes of anesthesia represent a probability of effectiveness on a subject at: causing the subject to lose consciousness and eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain. Anesthesia, as evidenced by google, is either local, general, or regional and the desired effects of anesthetic agents at the local, general, or regional level is evidenced by the definitions of general, local, and regional anesthesia; such as "General anesthesia puts the patient to sleep," (i.e. loss of consciousness) "local anesthesia numbs a specific body part. Regional anesthesia, such as spinal

anesthesia and epidural anesthesia, numbs the nerves that conduct sensation to a circumscribed body area." Therefore, a system that comprises a display monitor configured to depict drug concentrations, which represent a probability of effectiveness, where the drugs are anesthetic agents, represents drug concentrations with a probability of effectiveness where that effectiveness includes a subject at: causing the subject to lose consciousness and eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device Howson in view of Johnson by adding the sedative, analgesic and neuromuscular agents as taught by Teeple Jr. in order to make a more effective drug delivery system.

Response to arguments:

Applicant's arguments, filed 9/18/2007, with respect to the previous rejections under 35 USC 103 (a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

The above rejections under 35 USC 103 (a) are considered being newly made because they rely on and depend from the rejections made under 35 USC 102 (b) and comprise new reasoning for the rejections as stated above.

Double Patenting-Maintained-Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 6-11, 15, and 19 of copending

Application No. 10/269422 in view of Johnson et al (US P/N 5,522,798). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Howson et al fails to explicitly disclose that the drug monitor is configured to depict past, predicted and real-time probabilities of effectiveness. Johnson et al discloses a similar device, which does graphically depict past, predicted and real-time drug concentrations (col. 17. line 44 and col. 12 line 9), which read on past, predicted and real-time probabilities of effectiveness. Johnson et al., at col. 7, discloses how these concentrations are calculated based on drug data that may be uploaded, patient history data, or PK model data, all of which are used to calculate and deliver a particular drug concentration. The data that the calculations are dependent are based on correlations between concentrations and effectiveness. A patient's history data helps establish a record of what concentrations had what effects on a patient and enable a prediction of a concentration and an expected probability of effectiveness to be calculated based on this data, drug data, or PK model data. In other words, a display of a past, predicted, or real-time concentration of a drug, is a display of a past, predicted, or real-time probability of effectiveness since the calculations are based on known data that correlates concentrations, time, and effectiveness. Therefore, a drug monitor that graphically depicts past, predicted, and real-time drug concentrations are necessarily configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or

more drugs in the subject. Moreover, Johnson et al teaches that the display monitor is configured to depict a percent likelihood that the at least one drug has a desired effect based on results from a predefined population that is at least ninety-five percent of the population and wherein a plurality o inputs includes the height and weight of the subject (see col. 15 line 60).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Howson et al by incorporating the graphical drug concentration display of the type taught by Johnson et al in order to give the physician information in evaluating the need for changes in the desired drug concentration set point for a more accurate probability of effectiveness(col. 17 line 49).

This is a provisional obviousness-type double patenting rejection.

Response to arguments:

Applicant's arguments filed 9/18/2007 have been fully considered but they are not persuasive.

Applicant argues that obviousness-type double patenting rejection be held in abeyance until all other issues have been resolved.

Applicant's arguments are not found persuasive because it is in a since held in abeyance as it is a provisional obviousness-type double patenting rejection. This is a provisional double patenting rejection since the conflicting claims have not yet been patented and therefore, the rejection is being held to maintain a clear record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Borin can be reached via telephone (571)-272-0713.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

MICHAEL BORIN, PH.D
PRIMARY EXAMINER